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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/416,022	10/08/99	AGOURIDAS	C 146.1327

BIERMAN MUSERLIAN AND LUCAS
600 THIRD AVENUE
NEW YORK NY 10016

HM22/0109

EXAMINER

COLEMAN, B

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

01/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/416,022

Applicant(s)
AGOURIDAS et al.

Examiner
Brenda Coleman

Group Art Unit
1624



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-5 and 7-12 is/are rejected.

☒ Claim(s) 6 and 13 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-13 are pending in the application.

Specification

1. The disclosure is objected to because of the following informalities: The pages of the specification including claims and abstract must be numbered consecutively, starting with 1, the numbers being centrally located above or preferably, below, the text.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 and 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1-4 and 8-11 are vague and indefinite in that it is not known what is meant by the moiety $-C(=O)-Ar_2OR-(CH_2)_n-Ar$.
- b) Claim 7 is vague and indefinite in that the last species contains to close parenthesis which are unmatched. See line 16 and line 19 of page 2 of the claims.

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- c) Claims 10 and 11 indicate "comprising administering to warm-blooded animals an antibiotically effective amount" which is unclear as to whether this is indicative of a subject in need thereof.
- d) Claim 12 is vague and indefinite in that it is not known what is meant by the structure of formula III where the nitrogen atom is only substituted twice.
- e) Claim 12 is vague and indefinite in that it is not known what is meant by the phrase "the compound of the formulae" in lines 24 and 25 on page 5 of the claims, when only one formula follows.
- f) Claim 12 is vague and indefinite in that there is a definition for the variables R and B following the structure of formula IA, however, there is no variable R or B in the formula.
- g) Claim 12 recites the limitation " $-(CH_2)_n-Ar$ or $-C(=O)-Ar$ " in the definition of B. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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3. Claims 1-5 and 7-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Phan et al., WO 99/21871. Phan teaches the compounds, compositions and method of use of the instant invention where A is nitrogen; R, R₁ and R₂ are hydrogen; Hal is F, Cl or Br; and Z is hydrogen or -C(=O)-phenyl. See examples 1-3.

4. Claims 1-5 and 7-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Phan et al., U.S. 6,124,269. Phan teaches the compounds, compositions and method of use of the instant invention where A is nitrogen; R, R₁ and R₂ are hydrogen; Hal is F, Cl or Br; and Z is hydrogen or -C(=O)-phenyl. See examples 1-3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phan et al., U.S. 6,124,269 and WO 99/21871. The generic structure of Phan encompasses the instantly claimed compounds (see Formula I, column 2 of U.S. '269) and for the same uses (see column 1) as claimed herein. Examples 1-3 differ only in the nature of the R^p and X substituents. Column 2, line 57 defines the substituent X as F, Cl, Br or I and line 56 defines the substituent R^p as hydrogen or a hydroxy protecting group, where the hydroxy protecting group is as defined in

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line 66 in column 5 through line 12 in column 6 and in lines 51-55 of column 6. Compounds of the instant invention are generically embraced by Phan in view of the interchange ability of the R^p and X substituents of the [e.g. ketolide ring system]. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example I for X or acetyl for R^p as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

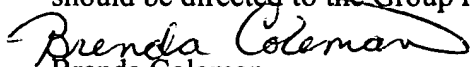
Claim Objections

6. Claims 6 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. None of the prior art of record nor a search in the pertinent art area teaches the substitution of the diazepine ring or the intermediates as claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Monday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Brenda Coleman
January 5, 2001